

US EPA ARCHIVE DOCUMENT

US ENVIRONMENTAL PROTECTION AGENCY
HUMAN STUDIES REVIEW BOARD
January 14, 2015 PUBLIC MEETING AGENDA

Internet Virtual Meeting

The meeting will be conducted at the following website:
<https://epa.connectsolutions.com/hsrb>

Wednesday, January 14, 2015

HSRB WEB SITE <http://www.epa.gov/osa/hsrb/>
Docket Telephone: (202) 566 1752
Docket Number: EPA-HQ-ORD-2014-0882

9:50 AM HSRB members login online

10:00 AM* **Convene Public Meeting** – Jim Downing, Designated Federal Officer, EPA
Human Studies Review Board, Office of the Science Advisor
Virtual Meeting operations –Rebecca Parkin, Ph.D., MPH, HSRB Chair
Introduction of Board Members –Rebecca Parkin, Ph.D., MPH, HSRB Chair
Opening Remarks – Toby Schonfeld, Ph.D., Human Subjects Research Review
Official, EPA

Session 1: Review and Approval of the HSRB Final Report of the November 5, 2014 Meeting

10:15 AM **Public Comments**

10:20 AM **Board Discussion of Draft Final Report**

Session 2: A published report: Ezratty, Veronique et al. (2014) Repeated Nitrogen Dioxide Exposures and Eosinophilic airway Inflammation in Asthmatics: A Randomized Crossover Study. *Environmental Health Perspectives*. Volume 122, Number 8, August 2014. (MRID 49519201)

10:40 AM **EPA Science Review Highlights** – LT Jonathan Leshin, Ph.D. (OPP, EPA)

10:50 AM **Board Questions of Clarification** – Rebecca Parkin, Ph.D., MPH (HSRB Chair),
EPA staff

11:05 AM **EPA Ethics Review Highlights** - Ms. Kelly Sherman (OPP, EPA)

11:15 AM **Board Questions of Clarification** – Rebecca Parkin, Ph.D., MPH (HSRB Chair),
and EPA staff

11:30 AM **Public Comments**

11:35 AM **Board Discussion**

*Agenda times are approximate and subject to change depending upon the discussion.

Charge to the Board - Science:

- Is this study scientifically sound, providing reliable data?
- If so, is this study adequate for quantitative use in support of an inhalation risk assessment for the use of nitrogen dioxide as a medical equipment sterilant?

Discussants: Randy Maddalena, Ph.D. (George Fernandez, statistics)

Charge to the Board - Ethics:

- Does the study meet the applicable requirements of 40 CFR part 26 subpart Q?

Discussant: Liz Heitman, Ph.D.

12:45 PM Lunch

1:30 PM Reconvene – roll call

Session 3: A published report: Spak, C.J. et al. (1989) Tissue Response of Gastric Mucosa after Ingestion of Fluoride. Karolinska Institute, Huddinge University Hospital, Huddinge, Sweden. *British Medical Journal*. 298:1686-7. (MRID 49489101)

1:35 PM EPA Science Review Highlights – Jaime D’Agostino, Ph.D., (Health Effects Division, OPP, EPA)

1:45 PM Board Questions of Clarification – Rebecca Parkin, Ph.D., MPH (HSRB Chair), EPA staff

2:00 PM EPA Ethics Review Highlights - Ms. Kelly Sherman (OPP, EPA)

2:10 PM Board Questions of Clarification – Rebecca Parkin, Ph.D., MPH (HSRB Chair), and EPA staff

2:25 PM Public Comments

2:35 PM Board Discussion

Charge to the Board - Science:

- Is this study scientifically sound, providing reliable data?
- If so, is this study adequate for quantitative use in support of an acute dietary risk assessment for fluoride?

Discussants: Ken Ramos, M.D., Ph.D. (Ed Gbur, Ph.D., statistics)

Charge to the Board - Ethics:

- Does the study meet the applicable requirements of 40 CFR part 26 subpart Q?

*Agenda times are approximate and subject to change depending upon the discussion.

Discussant: Jewel Halanych, M.D., M. Sc.

Session 4: A published report: **Hansson, T. and Roos, B. (1987). The Effect of Fluoride and Calcium on Spinal Bone Mineral Content: A Controlled, Prospective (3 years) study. Sahlgren's Hospital, University of Gothenberg, Sweden. *Calcified Tissue International*. 40:315-317. (MRID 49489102)**

3:25 PM EPA Science Review Highlights – Jaime D'Agostino, Ph.D., (Health Effects Division, OPP, EPA)

3:30 PM Board Questions of Clarification – Rebecca Parkin, Ph.D., MPH (HSRB Chair), EPA staff

3:45 PM EPA Ethics Review Highlights - Ms. Kelly Sherman (OPP, EPA)

3:55 PM Board Questions of Clarification – Rebecca Parkin, Ph.D., MPH (HSRB Chair), and EPA staff

4:10 PM Public Comments

4:15 PM Board Discussion

Charge to the Board - Science:

- Is this study scientifically sound, providing reliable data?
- If so, is this study adequate for qualitative use in support of an acute dietary risk assessment for fluoride?

Discussants: Will Pependorf, Ph. D. (Jun Zhu, Ph.D., statistics)

Charge to the Board - Ethics:

- Does the study meet the applicable requirements of 40 CFR part 26 subpart Q?

Discussant: Suzanne Rivera, Ph.D., M.S.W.

5:00 PM* Adjourn

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